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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,278	11/01/2001	Robert V. Farese JR.	407T-927110US	2111

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EXAMINER	
BERTOGLIO, VALERIE E	

ART UNIT	PAPER NUMBER
1632	6

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,278	FARESE ET AL.	
	Examiner	Art Unit	
	Valerie E. Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 27-37, drawn to a knockout mammal comprising a disruption in an endogenous *Ttpa* gene, classified in class 800, subclass 14.

II. Claims 12-26 and 38-42, drawn to a knockout mammal comprising disruptions in an endogenous *Ttpa* gene and an *apoE* gene, classified in class 800, subclass 14.

III. Claims 12-16 and 38-42, drawn to a knockout mammal comprising disruptions in an endogenous *Ttpa* gene and an APP gene, classified in class 800, subclass 14.

IV. Claims 43-53, drawn to a nucleic acid construct, classified in class 536, subclass 23.1.

V. Claims 53-56, drawn to a cell comprising a disruption in *Ttpa*, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the double transgenic does not require the single trangenic-both constructs can be injected at the same time to make the double transgenic. The single transgenic has separate utility such as a model of vitamin E deficiency.

Inventions I and III are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the double transgenic does not require the single trangenic-both constructs can be injected at the same time to make the double transgenic. The single transgenic has separate utility such as a model of vitamin E deficiency.

Inventions I and IV are patentably distinct because, the knockout mammal comprising a disruption in the *Ttpa* gene can be used as a model for vitamin E deficiency while the nucleic acid construct can be used as a DNA probe. The protocols and reagents required for the transgenic and the nucleic acid construct are materially distinct and separate. The burden required to search inventions I and IV together would be undue.

Inventions I and V are patentably distinct because, the transgenic can be used as an *in vivo* model for vitamin E deficiency while the cells can be used in *in vitro* assays for compounds that modulate αTTP pathway activity. The protocols and reagents required for the transgenic and the cells are materially distinct and separate. The burden required to search inventions I and V together would be undue.

Inventions II and III are patentably distinct because, the knockout mammal comprising a disruption in both the both *Ttpa* and *ApoE* genes can be used as a model for athersclerosis while the knockout mammal comprising a disruptions in both *Ttpa* and APP genes can be used to study interactions between *Ttpa* and APP. The *Ttpa/ApoE* double knockout does not require the *Ttpa/*APP double knockout and the *Ttpa/*APP double knockout does not require the *Ttpa/ApoE* double knockout. The burden required to search inventions II and III together would be undue.

Inventions II and IV are patentably distinct because, the knockout mammal comprising a disruption in both the both *Ttpa* and *ApoE* genes can be used as a model for athersclerosis while the nucleic acid construct can be used as a DNA probe. The protocols and reagents required for the transgenic and the nucleic acid construct are materially distinct and separate. The burden required to search inventions II and IV together would be undue.

Inventions II and V are patentably distinct because, the knockout mammal comprising a disruption in both the both *Ttpa* and *ApoE* genes can be used as a model for athersclerosis while the cells can be used in *in vitro* assays for compounds that modulate αTTP pathway activity. The protocols and reagents required for the transgenic and the cells are materially distinct and separate. The burden required to search inventions II and V together would be undue.

Inventions III and IV are patentably distinct because, the knockout mammal comprising a disruption in both the both *Ttpa* and APP genes can be used to study interactions between *Ttpa* and APP while the nucleic acid construct can be used as a DNA probe. The protocols and reagents required for the transgenic and the nucleic acid construct are materially distinct and separate. The burden required to search inventions III and IV together would be undue.

Inventions III and V are patentably distinct because, the knockout mammal comprising a disruption in both the both *Ttpa* and *ApoE* genes can be used to study interactions between *Ttpa* and APP while the cells can be used in *in vitro* assays for compounds that modulate αTTP pathway activity. The protocols and reagents required for the transgenic and the cells are materially distinct and separate. The burden required to search inventions III and V together would be undue.

Inventions IV and V are patentably distinct because, the nucleic acid construct can be used as a DNA probe while the cells can be used in *in vitro* assays for compounds that modulate αTTP pathway activity. The nucleic acid construct does not require the cells and the cells do not necessarily require the nucleic acid construct. The burden required to search inventions IV and V together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

MICHAEL C. WILSON
PATENT EXAMINER